

Remarks

Claims 1-20 are pending. Claim 12 has been canceled. Claims 1-10 have been withdrawn from consideration. Thus, claims 11 and 13-20 remain under consideration.

Claims 11 and 18 have been amended.

Applicants respectfully request reconsideration of the application in view of the claim amendments and the following remarks.

Amendments to the Claims

Please cancel claim 12 without prejudice.

Claim 11 has been amended to recite a transmucosal drug delivery device having a linear elastomeric polymer and a cross-linked elastomeric polymer in a ratio of about 1:2 to 5:1. This amendment is fully supported by the specification at, for example, page 7, lines 16-22 and original claim 2.

Claim 18 has been amended to correct a typographical error.

No new matter is introduced by these amendments.

§ 103 Rejections

Claims 11-20, of which claim 11 is the only independent claim, stand rejected under 35 USC § 103(a) as being unpatentable over U.S. Pat. No. 5,750,136 ("Scholz") in view of U.S. Pat. No. 5,527,610 ("Urry").

Claim 1 has been amended to recite that the transmucosal drug delivery device having a linear elastomeric polymer and a cross-linked elastomeric polymer in a ratio of about 1:2 to 5:1. The recited ratio of linear elastomeric polymer to cross-linked elastomeric polymer provides improved adhesive qualities and permits drug release profiles that can readily be altered as needed for the particular drug being delivered.

Applicants submit that the present rejection fails to establish a *prima facie* case of obviousness. § 706.02(j) of the M.P.E.P. states that in order to establish a *prima facie* case of obviousness, three basic criteria must be met:

- (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine the reference teachings;
- (2) there must be a reasonable expectation of success; and
- (3) the prior art references, when combined, must teach or suggest all of the claim limitations.

Specifically, Applicants' submit that one of ordinary skill in the art would not have been motivated to combine the teachings of Scholz and Urry to arrive at the subject matter recited in claim 1, as amended. Even if, for the sake of discussion, one of ordinary skill in the art had been motivated to combined Scholz and Urry as suggested in the Office Action, the combined references would not have provided the skilled person with a reasonable expectation of success. Finally, the combination of Scholz and Urry fails to teach or suggest all of the limitations of claim 1, as amended herein.

The Office Action acknowledges that Scholz does not specifically disclose bioadhesive compositions with a cross-linked polymer. The Office Action states that Urry discloses a bioelastomer that can comprise a cross-linked polymer. Urry is also said to disclose that cross-linking provides mechanical strength and rigidity to the polymer.

Neither Scholz nor Urry teaches a transmucosal drug delivery device having a composition that includes a *combination* of a linear elastomeric polymer and a cross-linked elastomeric polymer in a ratio of about 1:2 to 5:1. Urry teaches that the "bioelastomer can be uncross-linked or cross-linked." Column 5, lines 60-61. If the bioelastomer is cross-linked, Urry teaches that the extent of cross-linking can be modified according to the required mechanical strength and/or rigidity demanded by the ultimate use. The teaching of Urry relating to cross-linking providing mechanical strength and rigidity is limited to the extent of cross-linking within a cross-linked polymer. Nowhere does Urry teach or suggest that one use a combination of cross-linked and uncross-linked elastomeric polymers, as recited in claim 11. Moreover, neither Scholz nor Urry provides any teaching or suggestion of the functional qualities of an adhesive composition that includes a combination of linear elastomeric polymers and cross-linked elastomeric polymers.

Even if, for the sake of discussion, one of ordinary skill in the art would have attempted cross-linking the butyl rubber in the composition of Scholz to change the mechanical strength and/or rigidity of the composition – as suggested in the Office Action, combining the teachings of Scholz and Urry would not have led one to the subject matter of claim 1. One would simply have cross-linked the butyl rubber and obtained a cross-linked butyl rubber bioelastomer. One would not have obtained the composition recited in claim 1 – having a combination of a linear elastomeric polymer and a cross-linked elastomeric polymer in a ratio of about 1:2 to 5:1. The recited range of polymer ratios distinguishes Applicants' composition from the products of incomplete cross-linking reactions.

Finally, because neither Scholz, Urry, nor the combination of Scholz and Urry teaches or suggests a composition that includes a combination of linear elastomeric polymer and a cross-linked elastomeric polymer, the combination fails to teach or suggest a composition having a linear elastomeric polymer and a cross-linked elastomeric polymer in a ratio of about

1:2 to 5:1. The combination of cited references fails to teach or suggest the specified range of polymer ratios. Moreover, the combination of references fails to motivate one to attempt to obtain the specified ratio of polymers, whether by directly targeting the specified ratios or by the functional result of succeeding (e.g., improved adhesion).

Because the combination of Scholz and Urry (a) fails to teach or suggest all of the limitations of claim 11, as amended, (b) fails to motivate one of ordinary skill in the art to combine the references as suggested in the Office Action to obtain the subject matter of claim 11, and (c) fails to provide a reasonable expectation of success, the subject matter of claim 11 is not rendered obvious in light of the combination of Scholz and Urry.

The rejection of claims 11, as amended, under 35 USC § 103(a) as being unpatentable over Scholz in view of Urry has been overcome and should be withdrawn. Each of claims 13-20 depends, directly or indirectly, from claim 11 and is therefore patentable for at least all of the reasons set forth above regarding the patentability of claim 11.

In summary, the rejection of claims 11 and 13-20 under 35 USC § 103(a) as being unpatentable over Scholz in view of Urry has been overcome and should be withdrawn.

Conclusion

In view of the above, Applicants submit that the application is in condition for allowance. Reconsideration of the application and allowance of claims 11 and 13-20 is requested.

Respectfully submitted,



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